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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,772	03/18/2004	Ricardo Azpiroz	11696-070002	8113

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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,772	AZPIROZ ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,36,37 and 58-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,36,37 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9102004 & 3182004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 17, 36, 37, and 58-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 17, 36, and 37: the recitation, "isolated polynucleotide comprises a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof" renders the claims indefinite. It is unclear if the sequence is to have 85% identity to both any complement of SEQ ID NO: 1, and any segment of the complement, or if the polynucleotide is to comprise both a sequence having 85% identity to any complement of SEQ ID NO: 1, and any segment of that sequence. The metes and bounds of the claim are unclear.

In claim 37: the recitation, "wherein said first isolate polynucleotide is overexpressed and wherein said second isolated polynucleotide inhibits expression of said DWF4 polypeptide" renders the claim indefinite. It is unclear what is meant by "overexpressed", as opposed to expressed. Is the transcription rate of the first polynucleotide to be greater than that of the second polynucleotide?

In claims 78-80: the claims recite the limitation, "said vegetative tissue". There is insufficient antecedent basis for this limitation in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 17, 36, 37, and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17 is broadly drawn towards a method of modulating a DWF4 polypeptide in any host cell, comprising providing a host cell comprising a recombinant vector comprising (i) an isolated polynucleotide comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof; and (ii) a control element operably linked to said polynucleotide, whereby said polynucleotide can be transcribed, and culturing said cell under conditions whereby the polynucleotide is transcribed, wherein expression of said DWF4 polypeptide is inhibited. Claim 36 is broadly drawn to a method for producing a transgenic plant having any altered phenotype, comprising introducing an isolated polynucleotide into a plant cell, said polynucleotide comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof, producing a transgenic plant from said cell, said plant having any altered phenotype relative to the wild-type plant, wherein the isolated polynucleotide inhibits DWF4 polypeptide expression. Claim 37 is broadly drawn towards a method for producing a transgenic plant having any altered phenotype, comprising introducing first and second isolated polynucleotides into a plant cell, wherein said polynucleotides independently

comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof, said polynucleotides operably linked to at least first and second tissue-specific promoters, wherein said first polynucleotide is overexpressed and wherein said second polynucleotide inhibits expression of said DWF4 polypeptide; and producing a transgenic plant from said plant cell.

The specification describes the isolation and sequencing of the *Arabidopsis DWF4* gene (SEQ ID NO: 1), encoding the DWF4 polypeptide (SEQ ID NO: 2; page 48, line 16 to page 52, line 25). The specification indicates that the DWF4 polypeptide of SEQ ID NO: 2 is a cytochrome P450 monooxygenase (page 52, lines 27-29). OF NOTE: the specification appears to use both "*dwf4*" and "*DWF4*" to refer to the wild-type gene, set forth in SEQ ID NO: 1.

The specification at page 30, lines 24-28, indicates that the coding region begins at nucleotide position 1133 in SEQ ID NO: 1. Figure 2 describes the locations of exon, introns, 5' and 3' untranslated regions of the genomic clone, as well as the locations of four domains in DWF4 that are found in cytochrome P450 proteins. The specification at page 71, line 30 to page 72, line 10 indicates that a 1.1 kb region of the genomic clone upstream of the translation initiation start was used a the promoter fragment in *DWF4*-promoter::GUS constructs. The specification indicates that in brassinosteroid synthesis, there are at least two branched pathways leading to the end product, brassinolide. The specification at page 69, line 30 to page 70, line 7 indicates that the Arabidopsis DWF4 polypeptide is a 22α-hydroxylase that catalyzes the 22α-hydroxylation steps of the brassinolide (BL) biosynthetic pathways, and has as substrates campestanol and 6-oxocampestanol (Figure 1).

The claimed methods encompass a broad genus of isolated polynucleotides: any sequence

having at least 85% identity to the complement of any subsequence within SEQ ID NO: 1 and segments thereof. As discussed above, SEQ ID NO: 1 is a genomic clone, containing a promoter, introns, etc.

However, the specification does not teach any isolated polynucleotides having a sequence that is at least 85% identical to any sequence that is complementary to any subsequence of SEQ ID NO: 1, or segments thereof. The specification has not correlated the function of inhibiting DWF4 polypeptide expression with any sequence that is complementary to a non-coding sequence within SEQ ID NO: 1. The specification has not described the structure of any non-coding sequence of SEQ ID NO: 1 that is capable of inhibiting DWF4 polypeptide expression when expressed in antisense orientation.

The specification at page 54, line 25 to page 54, line 3 indicates that SEQ ID NO: 2 possesses four domains that are typical of cytochrome P450s. Sequences that have 85% identity to the complement of a subsequence that encodes any of these common domains have not been correlated with the function of inhibiting DWF4 polypeptide expression. As these domains are shared among cytochrome P450 enzymes, the isolated polynucleotide may instead inhibit expression of another P450 polypeptide, which confers a different phenotype to the host plant. The specification has not correlated the function of inhibiting particularly DWF4 polypeptide expression with any species of the genus of isolated polynucleotides that are complementary to only a subsequence of SEQ ID NO: 1, or that differs from any such complementary sequence by as much as 15%, and segments thereof.

Further regarding claim 37: the claim indicates that first and second isolated polynucleotides, both comprising sequences complementary to SEQ ID NO: 1, are operably

linked to first and second tissue-specific promoters. However, the specification as originally filed does not contemplate a method wherein two complementary sequences operably linked to first and second tissue-specific promoters are expressed. This embodiment is NEW MATTER and must be cancelled from the claims. Given the breadth of the claims and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of polynucleotide sequences encompassed by the claims.

3. Claims 17, 36, 37, and 58-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods wherein the isolated polynucleotide comprises a sequence that is a complement of the coding segments of SEQ ID NO: 1, does not reasonably provide enablement for the claimed method wherein the isolated polynucleotide comprises a sequence having at least 85% identity to a complement of SEQ ID NO: 1, or segments thereof that are non-coding sequences, or only portions of the coding sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 17 is broadly drawn towards a method of modulating a DWF4 polypeptide in any host cell, comprising providing a host cell comprising a recombinant vector comprising (i) an isolated polynucleotide comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof; and (ii) a control element operably linked to said polynucleotide, whereby said polynucleotide can be transcribed, and culturing said cell under conditions whereby the polynucleotide is transcribed, wherein expression of said DWF4

polypeptide is inhibited. Claim 36 is broadly drawn to a method for producing a transgenic plant having any altered phenotype, comprising introducing an isolated polynucleotide into a plant cell, said polynucleotide comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof, producing a transgenic plant from said cell, said plant having any altered phenotype relative to the wild-type plant, wherein the isolated polynucleotide inhibits DWF4 polypeptide expression. Claim 37 is broadly drawn towards a method for producing a transgenic plant having any altered phenotype, comprising introducing first and second isolated polynucleotides into a plant cell, wherein said polynucleotides independently comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof, said polynucleotides operably linked to at least first and second tissue-specific promoters, wherein said first polynucleotide is overexpressed and wherein said second polynucleotide inhibits expression of said DWF4 polypeptide; and producing a transgenic plant from said plant cell.

The specification describes the isolation and sequencing of the *Arabidopsis DWF4* gene (SEQ ID NO: 1), encoding the DWF4 polypeptide (SEQ ID NO: 2; page 48, line 16 to page 52, line 25). The specification indicates that the DWF4 polypeptide of SEQ ID NO: 2 is a cytochrome P450 monooxygenase (page 52, lines 27-29). OF NOTE: the specification appears to use both "*dwf4*" and "*DWF4*" to refer to the wild-type gene, set forth in SEQ ID NO: 1. Figures 2 and 10 describe the locations of exons, introns, 5' and 3' untranslated regions of the genomic clone, as well as the locations of four domains in DWF4 that are found in cytochrome P450 proteins. The specification at page 71, line 30 to page 72, line 10 indicates that a 1.1 kb region of the genomic clone upstream of the translation initiation start was used a the promoter

fragment in *DWF4*-promoter::GUS constructs. The specification indicates that in brassinosteriod synthesis, there are at least two branched pathways leading to the end product, brassinolide. The specification at page 69, line 30 to page 70, line 7 indicates that the Arabidopsis DWF4 polypeptide is a 22α-hydroxylase that catalyzes the 22α-hydroxylation steps of the brassinolide (BL) biosynthetic pathways, and has as substrates campestanol and 6-oxocampestanol (Figure 1).

However, as discussed above, SEQ ID NO: 1 itself comprises a genomic clone, containing non-coding sequences. The complete cDNA encoding a cytochrome P450 has been shown to inhibit expression of the encoded polypeptide when expressed in antisense orientation in transgenic plants (for example, Nair et al., Plant Physiol., 2000, Vol. 123, pages 1623-1634). However, one skilled in the art would not expect a polynucleotide comprising sequences that are complementary to non-coding portions of a gene to have the ability to inhibit expression of the encoded polypeptide. The DWF4 gene of SEQ ID NO: 1 contains 7 introns. SEQ ID NO: 1 consists of 6888 nucleotides, only 1539 of which encode the 513 amino acid sequence of SEQ ID NO: 2. Examples of methods, wherein promoter sequences, for instance, are expressed in antisense orientation to inhibit polypeptide expression, are lacking in the prior art. In the absence of further guidance, undue experimentation would be required by one skilled in the art to express SEQ ID NO: 1 or a polynucleotide comprising non-coding sequences of SEQ ID NO: 1 in antisense orientation to inhibit DWF4 polypeptide expression in a cell. SEQ ID NO: 1 also contains over 2 kb of sequences, over 30% of SEQ ID NO: 1, that are not part of the DWF4 gene, and which would have no effect on DWF4 polypeptide expression when expressed in antisense orientation in any cell.

Further, as discussed above, DWF4 contains domains that are shared among all

cytochrome P450 proteins, including those having differing functions. Antisense sequences of portions of SEQ ID NO: 1 encoding these domains, or of sequences that differ from the coding sequence of SEQ ID NO: 2 by as much as 15%, may inhibit expression of other P450 polypeptides instead. As discussed above, examples of expressing the complete cDNA encoding a P450 polypeptide in antisense orientation to inhibit expression of the encoded polypeptide specifically, has been shown. However, examples of the antisense expression of a portion of a P450 coding sequence, including portions of one of the common domains, to inhibit expression of a specific P450 protein, is lacking in the prior art and is not taught in the instant specification. Branch (Trends in Biochem. Sci., 1998, Vol. 23, pages 45-50) discusses how antisense sequences can affect unintended targets (pages 45-47). The specification does not teach what portions of SEQ ID NO: 1 would inhibit expression of DWF4, as opposed to other P450 polypeptides, when expressed in antisense orientation. In the absence of further guidance, undue experimentation would be required by one skilled in the art to express portions of SEQ ID NO: 1, or sequences differing therefrom by as much as 15%, or segments thereof, in antisense orientation, to inhibit the expression specifically of DWF4 polypeptide.

Further, claims 36 and 37 encompasses altering any plant phenotype. However, the specification teaches that inhibition of DWF4 expression causes a dwarf phenotype due to inhibition of cell elongation, that the primary effect is simply a reduction in the length of individual organs, exclusively along their normal growth axis, and that secondary effects of reduced cell elongation are themselves due to the reduction in cell length (page 58, 2nd full paragraph). In the absence of further guidance, undue experimentation would be required by one skilled in the art to alter other phenotypes by following the steps of the claimed methods.

Further, claim 17 encompasses inhibiting DWF4 expression in any host cell species. However, SEQ ID NO: 1 encodes a plant protein. The specification teaches how it affects cell elongation in plants, and teaches phenotypes that appear in plants when this protein is not expressed. However, the specification does not teach that expression of the isolated polynucleotide can inhibit DWF4 expression in non-plant cells, or what phenotype to expect even if any such homolog exists and is inhibited. In the absence of further guidance, undue experimentation would be required to determine species that comprise DWF4 homologs, and the effect of inhibiting expression therein. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 17, 36, 58-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choe et al. (Plant Cell, February 1998, Vol. 10, pages 231-244) in combination with Applicant's admitted state of the prior art.

It is noted that Applicants filed a declaration under 37 CFR 1.132, removing Choe et al. as a prior art reference, in parent application 09/502,426. However, it should be resubmitted for the instant application.

Claim 17 is broadly drawn towards a method of modulating a DWF4 polypeptide in any host cell, comprising providing a host cell comprising a recombinant vector comprising (i) an isolated polynucleotide comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof; and (ii) a control element operably linked to said polynucleotide, whereby said polynucleotide can be transcribed, and culturing said cell under conditions whereby the polynucleotide is transcribed, wherein expression of said DWF4 polypeptide is inhibited. Claim 36 is broadly drawn to a method for producing a transgenic plant having any altered phenotype, comprising introducing an isolated polynucleotide into a plant cell, said polynucleotide comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof, producing a transgenic plant from said cell, said plant having any altered phenotype relative to the wild-type plant, wherein the isolated polynucleotide inhibits DWF4 polypeptide expression.

Choe et al. teach the isolated DWF4 gene of Arabidopsis thaliana, the sequence of which is within instant SEQ ID NO: 1. Choe et al. teach the locations of exons and introns of the gene. Choe et al. also teach that brassinosteroids are important in plant growth promotion, and that DWF4 is a 22α-hydroxylase that provides the 22α-hyroxylase activity in the BL biosynthetic pathway. Choe et al. teach that dwf4 mutant plants are dwarfs (pages 233-236). Choe et al. also entered the sequence with GenBank in Accession No. AF044216, version released March 6, 1998.

Choe et al. do not teach antisense expression of sequences encoding DWF4 in cells.

Applicant's admitted state of the prior art teaches plant transformation vectors, promoters, and plant transformation techniques, and regeneration of plants from transformed plant cells (page 36, line 5 to page 39, line 14).

Any one of a number plant expression vectors, plant transformation and regeneration techniques could have been used, including those taught in Applicant's admitted state of the prior art. Any one of a variety of promoters may be used, including any of the promoters taught in Applicant's admitted state of the prior art. It would have been obvious that the transgenic plant would have a dwarf phenotype, as Choe et al. teach that mutant *dwf4* plants are dwarfs. If plant cells or protoplasts are transformed, it would have been obvious that the transformed cells would first be cultured *ex vivo*. The plant transformation techniques taught by Applicants' admitted state of the prior art include transformation of plants and plant cells. One would have been motivated to produce such transgenic plants, as a dwarf phenotype shorten breeding times, for example, which is desirable of economically important crop and ornamental plants.

5. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choe et al. (Plant Cell, February 1998, Vol. 10, pages 231-244) in combination with Purcell et al. (Plant J. 1998, Vol. 14, pages 195-202) and van der Meer et al. (Plant Mol. Biol., 1990, Vol. 15, pages 95-109).

Claim 37 is broadly drawn towards a method for producing a transgenic plant having any altered phenotype, comprising introducing first and second isolated polynucleotides into a plant cell, wherein said polynucleotides independently comprising a sequence having at least 85% identity to a complement of SEQ ID NO: 1 and segments thereof, said polynucleotides operably linked to at least first and second tissue-specific promoters, wherein said first polynucleotide is

overexpressed and wherein said second polynucleotide inhibits expression of said DWF4 polypeptide; and producing a transgenic plant from said plant cell.

Choe et al. is discussed above.

Choe et al. do not teach expressing two isolated polynucleotide sequences comprising sequences that are complementary to segments of SEQ ID NO: 1, operably linked to first and second tissue-specific promoters, in a transgenic plant.

Purcell et al. teach leaf- and stem-specific promoters (abstract, page 198).

van der Meer et al. teach a flower-specific promoter (abstract, pages 98-100).

It would have been obvious and within the scope of one of ordinary skill in the art to express the coding sequences from the DWF4 gene of Choe et al. in antisense orientation in transgenic plants to inhibit DWF4 polypeptide expression. The exons of the DWF4 gene represent segments of the complementary sequence of SEQ ID NO: 1. It would have been obvious to use tissue-specific promoters to limit the area of expression of the antisense sequence in the transgenic plant. One would have been motivated to do so to limit inhibition of DWF4 expression to only desired areas of the plant. It was also obvious that multiple expression cassettes, in which the antisense sequences are operably linked to different tissue-specific promoters, depending on one's desired end, could have been introduced into the transgenic plants. For example, it would have been obvious to introduce two expression cassettes into the plant, one in which the antisense sequences are operably linked to the promoters taught by Purcell et al., and another in which the sequences are operably linked to the promoter of van der Meer et al., to produce plants in which stems, leaves, and flowers are smaller. One would have

been motivated to do so, as such plants would have interest in the ornamental flower industry, for example.

6. All pending claims are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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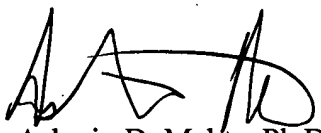

September 21, 2006

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Primary Examiner
Art Unit 1638